Consent Document Guidelines

Project Title: _____

IRB Number: _____

Principal Investigator: _____

INTRODUCTION

You are asked to take part in a research study conducted at [insert the study site] by [name(s) of investigator(s) (If a student, state how the study relates to your program of work, i.e. report, thesis, dissertation)]. Your participation in this study is voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Guidelines:

- Use simple language.
- Be Concise.
- Use the pronoun "you" consistently throughout (except for the signature of the subject on the last page)

PURPOSE OF THIS RESEARCH STUDY

This research study is intended to [explain the purpose of the research]. I/We hope to learn [state what the study is designed to discover or establish]. You were picked to take part in this study because [state why and how the subject was selected].

PROCEDURES

If you volunteer to take part in this study, you will be asked to do the following things:

Guidelines:

- Describe the procedures chronologically using lay language, short sentences, and short paragraphs. The use of table or flow diagrams will help to organize this section and increase readability.
- Distinguish which procedures are experimental and which are standard clinical treatments. Include screening evaluations and a listing of inclusion/exclusion criteria.
- Define and explain medical and scientific terms in ordinary language (for example, describing the amount of blood to be drawn in terms of teaspoons or tablespoons).
- Specify the number of subjects expected to be enrolled, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.
- For research involving randomization of subjects, specify the randomization process.
- For research involving the use of placebo, describe "placebo" in lay terms.

POTENTIAL RISKS OR DISCOMFORTS

Guidelines:

- Identify each procedure and then describe any reasonably foreseeable risks, discomforts, inconveniences, and how these will be minimized. If unknown, state so. If applicable, state that a particular treatment or procedure may involve currently unforeseeable risks (to the subject, embryo or fetus, for example.) Quantify risks using understandable comparisons.
- In addition to physiological risks and discomforts, describe any psychological, social, or legal risks that might result from participating in the research. Explain the extent to which data will be kept confidential. Address local or federal reporting requirements, if any. Inform the subject about availability of follow up or referral for treatment.
- Indicate if there are special risks to women of childbearing age; if relevant, state that study may involve risks that are currently unforeseeable, e.g., to developing fetus
- If subject's participation will continue over time, state: "any new information developed during the study that may affect your willingness to continue participation will be communicated to you."

POSSIBLE BENEFITS

Guidelines:

- Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the participant, explain possible benefits to others.
- If consent will be obtained from a legal representative of the subject, the direct benefit to the subject must be elaborated in the consent form.
- If there is no likelihood that participants will benefit directly from their participation in the research, state as much in clear terms. For example, "You should not expect any direct benefits for yourself from participating in this study."
- Do not include compensation or incentives in this section.

AVAILABLE TREATMENT ALTERNATIVES

Guidelines:

- Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If there are no effective alternatives, state that an alternative is not to participate in the study.
- If the prospective subjects are suffering from a terminal illness, and there are no alternative treatments available, you should say so; but add that treatment of symptoms and pain control are available through supportive care. In other words, avoid suggesting that participation in the research is the only way to obtain medical care and attention.
- If prospective subjects have a chronic, progressive disorder, or which no treatment had been demonstrated to be sage and effective, say that, as well. Also, describe opportunities for managing symptoms, improving ability to function, etc. so that it does not appear that the patient will be abandoned if he or she does not agree to participate.

COMPENSATION / INCENTIVES

Guidelines:

- State whether subjects will be paid or offered other benefits. If not, state so.
- If the subject will receive monies, describe the amount, when payment is scheduled, and prorated payment schedule should the subject decide to withdraw or be withdrawn by the investigator.
- If the subject will receive compensation other than money, describe it.
- If the subject will be reimbursed for expenses such as parking, bus/taxi, etc., state so.

CONFIDENTIALITY

Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised. [Describe how personal identities will be shielded, disguised, etc.]

However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, by any relevant governmental agency (e.g., Department of State Health Services), by the (your site name) Institutional Review Board, or by the persons conducting this study, (provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a court of competent jurisdiction. These records will be kept private as far as permitted by law.

Guidelines:

- Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel.
- Explain how specific consent will be requested, if any other uses are considered.
- If applicable, state when individual responses to survey questionnaires will be destroyed, following analyses of the data.

TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to take part in this study. If you choose not to take part in this study, it will not affect your right to health care or other services to which you are otherwise entitled. You will be told of any significant new findings developed during the course of this study that may influence your willingness to continue in this study. In the event you decide to stop your involvement in the study, please notify [name, telephone no., etc.] of your decision or follow this procedure [describe], so that your participation can be properly ended.

In addition, the investigator may terminate your participation in the study without your consent under the following circumstances. [Describe] It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the participants in the event that [Describe circumstances, such as loss of funding.]

AVAILABLE SOURCES OF INFORMATION

*For **questions about this study** call:*

Name:
Phone Number: [**include both a local and a toll free number**]

or

Principal Investigator: [**Name**]
Phone Number: [**Telephone Number**]

For questions you may have about your rights as a research subject call:

Department of State Health Services Institutional Review Board
1-888-777-5037

In case of a research-related emergency, call:

Day Emergency Number:
Night Emergency Number:

AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws. I also understand that I may withdraw from this study at any time without penalty.

Participant Name (Printed or Typed): _____

Date: _____

Participant Signature: _____

Date: _____

Principal Investigator Signature: _____

Date: _____

Person Obtaining Consent (Signature): _____

Date: _____